TFW

Level by certify that this correspondence is being deposited with the U.S. Postal Sorvice with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

22313-1430, Oil the date shown below

Dated: August 9, 2004 Signature: (Stephen P. Whelan)

Docket No.: 330498004US

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

David M. Hadley and Mustafa H. Sagiroglu

Application No.:

10/815,290

Con. No.: 8336

Filed:

March 30, 2004

Art Unit:

3736

For:

METHODS FOR QUANTIFYING THE

MORPHOLOGY AND AMPLITUDE OF

CARDIAC ACTION POTENTIAL

ALTERNANS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference on the PTO/SB/08 is attached.

Application No.: 10/815,290 Docket No.: 330498004US

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0665, under Order No. 330498004US.

Dated: Angust 9, 2004

Respectfully submitted,

Paul T. Parker

Registration No.: 38,264

PERKINS COIE LLP P.O. Box 1247 Seattle, Washington 98111-1247 (206) 359-8000

(206) 359-7198 (Fax) Attorney for Applicant

PTO/SB/21 (02-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number 10/815,290 - Conf. No. 8336

Filing Date March 30, 2004

First Named Inventor David M. Hadley

Art Unit 3736

Examiner Name Not Yet Assigned

Attorney Docket Number 330498004US

	·····		<u> </u>				
ENCLOSURES (Check all that apply)							
Fee Transmittal Form	Drawing(s)		After Allowance communication to Technology Center (TC)				
Fee Attached	Licensing-rela	ated Papers	Appeal Communication to Board of Appeals and Interferences				
Amendment/Reply [Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)				
After Final	Petition to Co		Proprietary Information				
Affidavits/declaration(s)		rney, Revocation rrespondence Address	Status Letter				
Extension of Time Request	Terminal Disc	claimer	X Other Enclosure(s) (please Identify below):				
Express Abandonment Request	Request for	Refund	Form PTO/SB/08 with Form PTO/SB/92 Certificate				
X Information Disclosure Statement	CD, Number	of CD(s)	2) Cited References (43)3) Return Receipt Postcard				
Certified Copy of Priority Document(s)	1						
Response to Missing Parts/ Incomplete Application	Remarks						
Response to Missing Parts under 37 CFR 1.52 or 1.53							
under 37 CFR 1.52 or 1.53							
SIGNATUR	RE OF APPLICA	NT, ATTORNEY, OR	AGENT				
Firm PERKINS COIE LLP Paul T. Parker - 38,264							
Signature Paul Parker							
Date August o	7. 2004						

	being deposited with the U.S. Postal Service with s Commissioner for Patents, P.O. Box 1450, Alexanda	
Dated: August 9, 2004	Signature: Mephin P. Whelan	(Stephen P. Whelan)

^{*} Number of Pages does not include Cited References



PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE spond to a collection of information unless it contains a valid OMB control number.

U.S. Patent and Trademark Office; U.S. ĎEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known				
Application Number 10/815,290 - Conf. No. 8336				
Filing Date	March 30, 2004			
First Named Inventor	David M. Hadley			
Art Unit	3736			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	330498004US			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		ACKERMAN, et al., "Ion Channels - Basic Science and Clinical Disease," New England Journal of Medicine, vol. 336 (22), pp. 1575-1586, 1977	
		ADAM, et al., "Estimation of Ventricular Vulnerability to Fibrillation Through T-Wave Time Series Analysis," Computers in Cardiology, pp. 307-310, September 1981	
		ADAM, et al., "Fluctuations in T-Wave Morphology and Susceptibility to Ventricular Fibrillation," Journal of Electrocardiology, vol. 17(3), pp. 209-218, 1984	
		ADAM, et al., "Ventricular Fibrillation and Fluctuations in the Magnitude of the Repolarization Vector," Computers in Cardiology, pp. 241-244, 1982	
		CARSON, et al., "Characterisation of unipolar waveform alternation in acutely ischaemic porcine myocardium," Cardiovascular Research, vol. 20, pp. 521-527, 1986	•
		CHINUSHI, et al., "Electrophysiological Basis of Arrhythmogenicity of QT/T Alternans in the Long-QT Syndrome - Tridimensional Analysis of the Kinetics of Cardiac Repolarization," Circulation Research, vol. 83 (6), pp. 614-628, Sept 21, 1998	
		CINCA, et al., "Mechanism and Time Course of the Early Electrical Changes During Acute Coronary Artery Occlusion - An Attempt to Correlate the Early ECG Changes in Man to the Cellular Electrophysiology in the Pig," Chest, vol. 77, pp. 499-505, April 1980	
		COETZEE, et al., "Effects of thiol-modifying agents on K _{ATP} channels in guinea pig ventricular cells," American Journal of Physiology, vol. 38, pp. H1625-H1633, 1995	
		CORONEL, et al., "Reperfusion arrhythmias in isolated perfused pig hearts - Inhomogeneities in extracellular potassium, ST and TQ potentials, and transmembrane action potentials," Circulation Research, vol. 71 (5), pp. 1131-1142, Nov 1992	
		DEMIDOWICH, et al., "Electrical alternans of the ST segment in non- Prinzmetal's angina," PACE, vol. 3, pp. 733-736, NovDec. 1980	
		Di BERNARDO, et al., "Effect of changes in heart rate and in action potential duration on the electrocardiogram T wave shape," Abstract only, Physiol Meas, vol. 23 (2), pp. 355-364, May 2002	

Examiner	Date	
Signature	Considered	

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO		Complete If Known			
				Application Number	10/815,290 - Conf. No. 8336
II.	NFORMATIO	N DI	SCLOSURE	Filing Date	March 30, 2004
S	STATEMENT BY APPLICANT			First Named Inventor	David M. Hadley
				Art Unit	3736
	(Use as many sheets as necessary)		Examiner Name	Not Yet Assigned	
Sheet	2	of	4	Attorney Docket Number	330498004US

	DUCKETT, et al., "Modeling the Dynamics of Cardiac Action Potentials," Physical Review Letters, vol. 84 (4), pp. 884-887, July 24, 2000	
	GIMA, et al., "Ionic Current Basis of Electrocardiographic Waveforms - A Model Study," Circulation Research, vol. 90, pp. 889-896, May 2002	,
	HAN, "Ventricular vulnerability during acute coronary occlusion," American Journal of Cardiology, vol. 24, pp. 857-864, December 1969	
•	HAN, et al., "Temporal dispersion of recovery of excitability in atrium and ventricle as a function of heart rate," American Heart Journal, vol. 71 (4), pp. 481-487, April 1966	
	HASHIMOTO, et al., "Effects of calcium antagonists on the electrical alternans of the ST segment and on associated mechanical alternans during acute coronary occlusion in dogs," Circulation, vol. 68 (3): 667-672, Sept. 1983	
	HASHIMOTO, et al., "Effects of the ventricular premature beat on the alternation of the repolarization phase in ischemic myocardium during acute coronary occlusion in dogs," Abstract only, Journal of Electrocardiology, vol. 17 (3), pp. 229-238, July 1984	
	HELLERSTEIN, et al., "Electrical alternation in experimental coronary artery occlusion," American Journal of Physiology, vol. 160, pp. 366-374, Feb. 1950	
	KASS, et al., "Channel structure and drug-induced cardiac arrhythmias," PNAS, vol. 97 (22), pp. 11683-11684, October 24, 2000	
	KAŽIĆ et al., "Ion Channels and Drug Development - Focus on Potassium Channels and Their Modulators," Medicine and Biology, Vol 6 (1), pp. 23 - 30, 1999	
	KLEINFELD, et al., "Alternans of the ST Segment in Prinzmetal's Angina," Circulation, vol. 55 (4), pp. 574-577, April 1977	
-	KLEINFELD, et al., "Electrical alternans of components of action potential," American Heart Journal, vol. 75 (4), pp. 528-530, April 1968	
	KONTA, et al., "Significance of discordant ST alternans in ventricular fibrillation," Circulation, vol. 82 (6), pp. 2185-2189, Dec. 1990	
	KUBOTA, et al., "Role of ATP-Sensitive K* Channel of ECG ST Segment During a Bout of Myocardial Ischemia - A Study of Epicardial Mapping in Dogs," Circulation, vol. 88 (4, Part 1), pp. 1845-1851, Oct. 1993	•

Examiner	Date
Signature	Considered
o ignoral o	Considered

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO		Complete If Known			
				Application Number	10/815,290 - Conf. No. 8336
II.	NFORMATION	1 DI	SCLOSURE	Filing Date	March 30, 2004
S	STATEMENT BY APPLICANT		First Named Inventor	David M. Hadley	
				Art Unit	3736
	(Use as many sheets as necessary)		Examiner Name	Not Yet Assigned	
Sheet	3	of	4	Attorney Docket Number	330498004US

KURZ, et al., "Ischaemia induced alternans of action potential duration in the intact-heart: dependence on coronary flow, preload and cycle length," European Heart Journal, vol. 14, pp. 1410-1420, 1993	
LUKAS, et al., "Differences in the electrophysiological response of canine ventricular epicardium and endocardium to ischemia: Role of the transient outward current," Circulation, vol. 88 (6), pp. 2903-2915, Dec.1993	
MOODY, et al., "Clinical Validation of the ECG-Derived Respiration (EDR) Technique," Computers in Cardiology, pp. 507-510, 1986	
NAKASHIMA, et al., "Experimental studies and clinical report on the electrical alternans of ST segment during myocardial ischemia," Japanese Heart Journal, vol. 19 (3) pp. 396-408, May 1978	
NEARING, et al., "Dynamic Tracking of Cardiac Vulnerability by Complex Demodulation of the T Wave," Science, vol. 252, pp. 437-440, April 1991	
NEARING, et al., "Modified moving average analysis of T-wave alternans to predict ventricular fibrillation with high accuracy," Journal of Applied Physiology, vol. 92, pp. 541-549, Feb. 2002	
NEARING, et al., "Tracking States of Heightened Cardiac Electrical Instability by Computing Interlead Heterogeneity of T-Wave Morphology Using Second Central Moment Analysis," J Appl Physiol, vol. 95, pp. 2265-2272, Dec 2003., 41 pages (First published August 1, 2003; 10.1152/japplphysiol.00623.2003)	
PASTORE, et al., "Mechanism Linking T-Wave Alternans to the Genesis of Cardiac Fibrillation," Circulation, vol., 99, pp. 1385-1394, Mar. 1999	
RAEDER, et al., "Alternating Morphology of the QRST Complex Preceding Sudden Death," New England Journal of Medicine, vol. 326 (4), pp. 271-272, Jan. 23, 1992	
RING, et al., "Exercise-Induced ST Segment Alternans," American Heart Journal, vol. 111 (5), pp. 1009-1011, May 1986	
RODEN, et al., "Cardiac Ion Channels," Annual Review Physiology, vol. 64, pp. 431-475, 2002	/
SALERNO, et al., "Ventricular arrhythmias during acute myocardial ischaemia in man. The role and significance of R-ST-T alternans and the prevention of ischaemic sudden death by medical treatment," European Heart Journal, vol. 7 Suppl A, pp. 63-75, 1986	
SCHRAM, et al., "Differential Distribution of Cardiac Ion Channel Expression as a Basis for Regional Specialization in Electrical Function," Circulation Research, vol. 90, pp. 939-950, May 2002	

Examiner	Date
Signature	Considered Considered

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO		Complete If Known			
				Application Number	10/815,290 - Conf. No. 8336
II.	IFORMATION	N DIS	CLOSURE	Filing Date	March 30, 2004
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	David M. Hadley
				Art Unit	3736
(Use as many sheets as necessary)		Examiner Name	Not Yet Assigned		
Sheet	4	of	4	Attorney Docket Number	330498004US

SMITH, et al., "Electrical Alternans and Cardiac Electrical Instability," Circulation, vol. 77 (1), pp. 110-121, Jan. 1988
SMITH, et al., "Subtle Alternating Electrocardiographic Morphology as an Indicator of Decreased Cardiac Electrical Stability," Computers in Cardiology, pp. 109-112, 1985
VERRIER, et al., "Risk Identification by Noninvasive Markers of Cardiac Vulnerability," Foundations of Cardiac Arrhythmias-Basic Concepts and Clinical Approaches, P. Spooner and M. Rosen (eds.), Marcel Dekker, Inc., pp. 745-777, 2000
VERRIER, et al., "Electrophysiologic Basis for T Wave Alternans as an Index of Vulnerability to Ventricular Fibrillation," Journal of Cardiovascular Electrophysiology, Vol. 5, pp. 445-461, May 1994
WALKER, et al., "Repolarization alternans: implications for the mechanism and prevention of sudden cardiac death," Abstract only, Cardiovascular Research, vol. 57 (3), pp. 599-614, Mar. 2003
WAYNE, et al., "Exercise-induced ST segment alternans," Chest, vol. 83 (5), pp. 824-825, May 1983

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Considered	i

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/92 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Application No. (if known): 10/815,290

Attorney Docket No.: 330498004US

Certificate of Mailing under 37 CFR 1.8

I hereby certify that this Form PTO/SB/08 (4 pages) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

> MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

August 9, 2004 . Date

Stephen P. Whelan Typed or printed name of person signing Certificate